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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,028	12/14/2004	Giancarlo Rizzoli	2579.011US1	4654

21186 7590 05/21/2010

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EXAMINER	
BARHAM, BETHANY P	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
05/21/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com
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Office Action Summary	Application No.	Applicant(s)	
	10/510,028	RIZZOLI ET AL.	
	Examiner	Art Unit	
	BETHANY BARHAM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,10,17,21,26 and 31-56* is/are pending in the application.

4a) Of the above claim(s) *26,37 and 52-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,10,17,21,31-36 and 38-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/15/10, 03/10/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of IDS's filed on 02/15/10 and 03/10/10 is acknowledged. Receipt of Applicant's response and claim amendments filed on 02/15/10 is also acknowledged. Claims 1-4, 10, 17, 21, 26, and 31-56 are pending. Claims 26, 37 and 52-56 remain withdrawn. Claims 1-4, 10, 17, 21, 31-36 and 38-51 are rejected. Note: Applicant previously elected (a) alpha-tricalcium phosphate and (b) glycosaminoglycan with less than 99% water, a molecular weight larger than 300,000 and a weight relationship A/B of 0.2-0.5 on 07/23/09.

Due to the claim amendments the previous objections and many of the 112 2nd rejections are hereby withdrawn, with the exception of indefinite rejection over claim 40. All other rejections of record are maintained.

MAINTAINED REJECTIONS

DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 21, 31-36, and 38-39 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 19-21, 27-31, 33-34 and 36 of U.S. Patent No. US 6,733,582 ('582). Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a composition comprising a calcium phosphate particle such as alpha-tricalcium phosphate ('582 claim 3) with an overlapping a particle size of 100-250 microns ('582 claims 27-29), overlapping Ca/P ratio of 1-2 ('582 claims 33-34 (Ca/P 1-1.67)), and hyaluronic acid or hyaluronate salts, etc. and '582 further claims a hydrophobic liquid in claim 36 (which is a pore former (col. 5, lines 36-41) making it porous.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 40 recites the limitation "wherein a concentration of the ready-to-use, hydrated hydrogel or a ready-to-use, hydrated substance which can be swellen into a

hydrogel" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 17, 21, 31-36, and 38-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 0141824 (citing from equivalent patent US 6,733,582 ('582)) in view of US 5,510,418 ('418) and further in view of US 2002/0187104 ('104), US 5,290,494 ('494) and US 6,117,456 ('456).

The instant claims are directed to a kneadable and moldable bone-replacement material which consists of a mixture of: A) calcium-containing ceramic particles wherein the ceramic particles comprise a calcium- phosphate ratio having a molar Ca/P relationship between 1.0 and 2.0, wherein the calcium phosphate is selected from the following group: : Dicalcium-phosphate-dihydrate (CaHPO4 x 2 H20), dicalcium-phosphate (CaHPO4), alpha-tricalcium-phosphate (alpha-Ca3(PO4)2), beta- tricalcium-phosphate (beta-Ca3(PO4)2), calcium-deficient hydro-xylapatite (Ca9(PO4)5(HPO4)OH), hydro-xylapatite (CA10(PO4)6OH)2), carbonated apatite (Ca10(PO4)3(CO3)3(OH)2), flouride-apatite (Cal0(PO4)6(F,OH)2), chloride-apatite

(Cal0 (PO4)6(C1,OH)2), whitlockite ((Ca,Mg)3(PO4)2), tetracalcium-phosphate (Ca4(PO4)20), oxyapatite (CA10(PO4)60), beta-calcium-pyrophosphate (beta-Ca2(P207), alpha-calcium- pyrophosphate, gamma-calcium-pyrophosphate, octo-calcium-phosphate (Ca8H2(PO4)6 x 5 H20), wherein a bulk density of the ceramic particles is between 0.6 g/ccm and 1.0 g/ccm, and wherein an average diameter of the ceramic particles is between 100 and 250 micrometers; and B) a hydrogel or a substance that can be swelled into a hydrogel, and wherein: C) the ceramic particles are of fully synthetic origin; D) the individual ceramic particles have at least a partially cohesive, porous structure; and E) the majority of the ceramic particles have a non-spheric shape.

- '582 teaches a bone replacement composition comprising particles of 0.1-100 microns of alpha-tricalcium phosphate (α-TCP) granules of 100-500 microns in size of calcium phosphates such as α-TCP (col. 3, lines 22-45; col. 4, lines 20-26), with a Ca/P ratio of 1-1.67 (abstract, col. 4, line 58-col. 5, line 3; claims 1, 3, 27-31 and 33). According to '582 the composition can additionally contain a biodegradable polymer such as hyaluronic acid or hyaluronate salts to increase viscosity of the composition (col. 5, lines 5-15; claims 19-21). Example 4 makes a composition with TCP granules of 125-1000 microns and a solution of hyaluronic acid in the amount instant claimed in claim 40. According to '582 a hydrophobic liquid is added to the composition to form pores and further according to '582 porosity can be increased with an increase in the volume of the

third component (col. 4, lines 38-52; col. 5, lines 36-45; claim 36) (meeting the limitations of instant claims 1, 21, 40 and 43-45).

- '582 teaches including magnesium salts or strontium ions (abstract, claim 1 and 39) (meeting the limitations of instant claim 31).

'582 does not teach the particle/granule shape, density or the porosity of the calcium phosphate of instant claim 1-4 and 17 or the source or molecular weight of the hyaluronic acid of claims 32-36, 38-39 and 41-48.

- '418 teaches that suitable particulate material such as TCP with a diameter of 20-250 microns can be irregular in shape (col. 13, lines 13-24) (according to the limitations of claims 1-4 and 17).
- '418 teaches that glycosaminoglycans such as hyaluronic acid are in general extracted from natural sources but that they may be synthetically produced or synthesized by microorganisms and that the composition is a polymer of
    - -(C8H13O4N)n-(C6H8O5)n-O-, where n=1 to 5000, which overlaps with the instant claimed molecular weight ranges (meeting the limitations of claims 32-36, 38-39 and 41-48).

'582 and '418 do not teach the density or the porosity of the calcium phosphate of instant claims 1.

- '104 teaches that TCP with a Ca/P ratio of 1-1.5 and a particle size of 100 microns to 1 mm are macroporous with pores of 30-200 microns in size [0017, 0024-0025] (according to the limitations of claims 1).

'582, '418, and '104 do not teach the density the calcium phosphate of instant claim 1.

- '494 teaches porous particulate resorbable TCP material with densities of 1.02 g/cm^3 and 0.6 gm/cm^3 (Example 8 and 9) (meeting the limitations of claim 1).
- According to '456, the parameters of density and porosity can be adjusted alone or in combination as require by specific applications. Slow resorption (greater than three months) is favored by the use of high density, low porosity calcium phosphate and/or rapid reaction and hardening times. Fast resorption (three or less months) is favored by the use of low density, high porosity calcium phosphate, and/or slow reaction and setting times. Guidance for adjustment of rate and completeness of reaction to form the calcium phosphate are given elsewhere herein (col. 9, lines 2-25).
- Note the specific gravity of the composition is not taught but a composition comprising granules of TCP and hyaluronic acid in the amounts and particle sizes claimed would naturally have the instant claimed specific gravity (instant claim 49).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the composition of '582 and use the techniques of '418 to shape the particles of '582 with predictable results. A person of ordinary skill in the art would know how to substitute known density of TCP of '494 and known porosity of TCP of '104 into the specific α-TCP composition of '582 in view of '418 with predictable results. The simple substitution of a known component for another is within the purview of the skilled artisan and would yield predictable results. Furthermore, as taught by '456 the parameters of density and porosity can be adjusted alone or in combination as require

by specific applications and a person of ordinary skill in the art desiring to make a bone replacement composition with fast resorption would know to use low density, high porosity calcium phosphate, specifically of '104 and '494 in the composition of '582 in view of '418 with a reasonable expectation of success. One of ordinary skill in the art would know how to optimize the ranges of '104, '494 and '456, as the MPEP 2144.05 states "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Claims 1-4, 10, 17, 21, 31-36, and 38-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 0141824 (citing from equivalent patent 6,733,582 ('582)) in view of US 5,510,418 ('418) and further in view of US 6,210,715 ('715), US 5,290,494 ('494) and US 6,117,456 ('456).

- '582 and '418 are taught above and teaches a bone replacement composition comprising as hyaluronic acid or hyaluronate salts and particles of 0.1-100 microns of alpha-tricalcium phosphate (α-TCP) granules of 100-500 microns in size of calcium phosphates such as α-TCP (col. 3, lines 22-45; col. 4, lines 20-26), with a Ca/P ratio of 1-1.67 (abstract, col. 4, line 58-col. 5, line 3; claims 1, 3, 27-31 and 33).
- '418 teaches that suitable particulate material such as TCP with a diameter of 20-250 microns can be irregular in shape (col. 13, lines 13-24) (according to the limitations of claims 1-4 and 17).

- '418 teaches that glycosaminoglycans such as hyaluronic acid are in general extracted from natural sources but that they may be synthetically produced or synthesized by microorganisms and that the composition is a polymer of
    - -(C8H13O4N)n-(C6H8O5)n-O-, where n=1 to 5000, which overlaps with the instant claimed molecular weight ranges (meeting the limitations of claims 32-36, 38-39 and 41-48).

'582 and '418 do not teach the density or the porosity of the calcium phosphate of instant claims 1, and 10.

- '715 teaches that microspheres of CaP (calcium phosphate) for implantation have a porosity of about 60% with a pore size of 350-500 microns (abstract, col. 9, lines 2-5) (meeting the limitations of instant claims 1, and 10).

'582, '418, and '104 do not teach the density the calcium phosphate of instant claim 1.

- '494 teaches porous particulate resorbable TCP material with densities of 1.02 g/cm^3 and 0.6 gm/cm^3 (Example 8 and 9) (meeting the limitations of claim 1).
- According to '456, the parameters of density and porosity can be adjusted alone or in combination as require by specific applications. Slow resorption (greater than three months) is favored by the use of high density, low porosity calcium phosphate and/or rapid reaction and hardening times. Fast resorption (three or less months) is favored by the use of low density, high porosity calcium phosphate, and/or slow reaction and setting times. Guidance for adjustment of rate and completeness of reaction to form the calcium phosphate are given elsewhere herein (col. 9, lines 2-25).

- Note the specific gravity of the composition is not taught but a composition comprising granules of TCP and hyaluronic acid in the amounts and particle sizes claimed would naturally have the instant claimed specific gravity (instant claim 49).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the composition of '582 and use the techniques of '418 to shape the particles of '582 with predictable results. A person of ordinary skill in the art would know how to substitute known density of TCP of '494 and known porosity of TCP of '715 into the specific α-TCP composition of '582 in view of '418 with predictable results. The simple substitution of a known component for another is within the purview of the skilled artisan and would yield predictable results. Furthermore, as taught by '456 the parameters of density and porosity can be adjusted alone or in combination as require by specific applications and a person of ordinary skill in the art desiring to make a bone replacement composition with fast resorption would know to use low density, high porosity calcium phosphate, specifically of '715 and '494 in the composition of '582 in view of '418 with a reasonable expectation of success. One of ordinary skill in the art would know how to optimize the ranges of '715, '494 and '456, as the MPEP 2144.05 states "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Claims 1-4, 17, 21, 31-36, and 38-51 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2001/0053938 ('938) (as cited in Applicant's IDS) in view of US

5,510,418 ('418) and further in view of US 2002/0187104 ('104), US 5,290,494 ('494) and US 6,117,456 ('456).

- '938 teaches a paste composition for bone replacement comprising granules of 50 microns-5mm of tricalcium phosphate (TCP) and hyaluronic acid in a ratio of A/B of 0.3333 (or 1/3) (abstract, claims 1, 7-11 and 50-51).
- '938 teaches that the TCP can be porous [0024].

'938 does not teach the particle/granule shape, density or the porosity of the calcium phosphate of instant claim 1-2, 5 and 17 or the source or molecular weight of the hyaluronic acid of claims 32-36, 38-39 and 41-48.

- '418 teaches that suitable particulate material such as TCP with a diameter of 20-250 microns can be irregular in shape (col. 13, lines 13-24) (according to the limitations of claims 1-5 and 17).
- '418 teaches that glycosaminoglycans such as hyaluronic acid are in general extracted from natural sources but that they may be synthetically produced or synthesized by microorganisms and that the composition is a polymer of
    - -(C8H13O4N)n-(C6H8O5)n-O-, where n=1 to 5000, which overlaps with the instant claimed molecular weight ranges (meeting the limitations of claims 32-36, 38-39 and 41-48).

'938 and '418 do not teach the density or the porosity of the calcium phosphate of instant claims 1.

- '104 teaches that TCP with a Ca/P ratio of 1-1.5 and a particle size of 100 microns to 1 mm are macroporous with pores of 30-200 microns in size [0017, 0024-0025] (according to the limitations of claims 1).

'938, '418, and '104 do not teach the density the calcium phosphate of instant claim 1.

- '494 teaches porous particulate resorbable TCP material with densities of 1.02 g/cm^3 and 0.6 gm/cm^3 (Example 8 and 9) (meeting the limitations of claim 1).
- According to '456, the parameters of density and porosity can be adjusted alone or in combination as require by specific applications. Slow resorption (greater than three months) is favored by the use of high density, low porosity calcium phosphate and/or rapid reaction and hardening times. Fast resorption (three or less months) is favored by the use of low density, high porosity calcium phosphate, and/or slow reaction and setting times. Guidance for adjustment of rate and completeness of reaction to form the calcium phosphate are given elsewhere herein (col. 9, lines 2-25).
- Note the specific gravity of the composition is not taught but a composition comprising granules of TCP and hyaluronic acid in the amounts and particle sizes claimed would naturally have the instant claimed specific gravity (instant claim 49).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the composition of '582 and use the techniques of '418 to shape the particles of '938 with predictable results. A person of ordinary skill in the art would know how to substitute known density of TCP of '494 and known porosity of TCP of '104 into

the specific TCP composition of '938 in view of '418 with predictable results. The simple substitution of a known component for another is within the purview of the skilled artisan and would yield predictable results. Furthermore, as taught by '456 the parameters of density and porosity can be adjusted alone or in combination as require by specific applications and a person of ordinary skill in the art desiring to make a bone replacement composition with fast resorption would know to use low density, high porosity calcium phosphate, specifically of '104 and '494 in the composition of '938 in view of '418 with a reasonable expectation of success. One of ordinary skill in the art would know how to optimize the ranges of '104, '494 and '456, as the MPEP 2144.05 states "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

Claims 1-4, 10, 17, 21, 31-36, and 38-51 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2001/0053938 ('938) in view of US 5,510,418 ('418) and further in view of US 6,210,715 ('715), US 5,290,494 ('494) and US 6,117,456 ('456).

- '938 and '418 are taught above and '938 teach a paste composition for bone replacement comprising granules of 50 microns-5mm of tricalcium phosphate (TCP) and hyaluronic acid in a ratio of A/B of 0.3333 (or 1/3) (abstract, claims 1, 7-11 and 50-51) and '418 teaches that suitable particulate material such as TCP with a diameter of 20-250 microns can be irregular in shape (col. 13, lines 13-24) (according to the limitations of claims 1-4 and 17).

'938 and '418 do not teach the density or the porosity of the calcium phosphate of instant claims 1, and 10.

- '715 teaches that microspheres of CaP (calcium phosphate) for implantation have a porosity of about 60% with a pore size of 350-500 microns (abstract, col. 9, lines 2-5) (meeting the limitations of instant claims 1, 10).

'582, '418, and '104 do not teach the density the calcium phosphate of instant claim 1.

- '494 teaches porous particulate resorbable TCP material with densities of 1.02 g/cm^3 and 0.6 gm/cm^3 (Example 8 and 9) (meeting the limitations of claim 1).
- According to '456, the parameters of density and porosity can be adjusted alone or in combination as require by specific applications. Slow resorption (greater than three months) is favored by the use of high density, low porosity calcium phosphate and/or rapid reaction and hardening times. Fast resorption (three or less months) is favored by the use of low density, high porosity calcium phosphate, and/or slow reaction and setting times. Guidance for adjustment of rate and completeness of reaction to form the calcium phosphate are given elsewhere herein (col. 9, lines 2-25).
- Note the specific gravity of the composition is not taught but a composition comprising granules of TCP and hyaluronic acid in the amounts and particle sizes claimed would naturally have the instant claimed specific gravity (instant claim 49).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the composition of '938 and use the techniques of '418 to shape the

particles of '938 with predictable results. A person of ordinary skill in the art would know how to substitute known density of TCP of '494 and known porosity of TCP of '715 into the specific TCP composition of '938 in view of '418 with predictable results. The simple substitution of a known component for another is within the purview of the skilled artisan and would yield predictable results. Furthermore, as taught by '456 the parameters of density and porosity can be adjusted alone or in combination as require by specific applications and a person of ordinary skill in the art desiring to make a bone replacement composition with fast resorption would know to use low density, high porosity calcium phosphate, specifically of '715 and '494 in the composition of '938 in view of '418 with a reasonable expectation of success. One of ordinary skill in the art would know how to optimize the ranges of '715, '494 and '456, as the MPEP 2144.05 states "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Response to Arguments

Applicant's arguments with respect to claims 1-4, 10, 17, 21, 31-36 and 38-51 have been considered but are not persuasive. Applicant argues that the obviousness double patenting should be withdrawn due to 'a number of distinguishing limitations'. Applicant argues that '582 does not teach a porous structure, to which the Examiner respectfully directs Applicant to claim 36 which claims a hydrophobic liquid (which according to col. 5 create pores in the composition). Secondly the Applicant argues that '582 does not claim the 'use of a hydrogel', the Examiner would like to respectfully point

out the instant claims do not claim 'use of a hydrogel' but rather "B) a hydrogel or a substance that can be swelled into a hydrogel" (instant claim 1) and Applicant has elected glycosaminoglycan and according to instant claim 39 glycosaminoglycan can be hyaluronic acid, which '582 claims a polymer for rheology modification such as hyaluronic acid. As such the Examiner respectfully puts forth that '582 claims hyaluronic acid which reads on the instant claimed glycosaminoglycan hydrogel. Further Applicant argues that '582 does not have particles of non-spheric shape. The Examiner respectfully points out that the instant claims do not require that all particles have a non-spheric shape but rather that a 'majority' of particles have a non-spheric shape meaning that some particles are or can be spheric in shape and the claimed particles of '582 have the same composition the same particles size and are not taught to be spherical and thus overlap with the instant claimed particles.

Applicant's argue that the prior art of record does not teach a hydrogel or a substance that can be swelled into a hydrogel. The Examiner respectfully disagrees as Applicant's have elected glycosaminoglycan and according to instant claim 39 glycosaminoglycan can be hyaluronic acid, which both '582 and '938 claim a polymer for rheology modification or bonding, respectively, such as hyaluronic acid. Applicant's argue that "a hydrogel microstructure requires includes a degree of crosslinking that provides structure and desirable mechanical properties". Both '582 and '938 claim hyaluronic acid in their bone replacement composition and Applicant's argument that hyaluronic acid is not a hydrogel is not persuasive as Applicant claims in claims 39 and 43 simply 'hyaluronic acid' or 'liquid solution of a hyaluronate' without any statement or

claim to crosslinking. Further cited as interest and support for the fact that hyaluronic acid is a hydrogel the Examiner Cites as Interest US 2003/0143283 which states "hydrogel such as a hyaluronate" for bone replacement (abstract) and Chen et al which states that "hydrogels of natural polymers especially polysaccharides have been used widely" and that "hyaluronate tends to form gels which are mucoadhesive" (pg. 69, col. 2, 1st paragraph; pg. 71, col. 1, last paragraph; and also see Table1 and Fig. 2 which show hyaluronate (or hyaluronic acid)). As such the prior art of record and cite as interest teaches hyaluronic acid which is a natural polysaccharide is a hydrogel and gels or increases viscosity or is viscous and thus is "a hydrogel or a substance that can be swelled into a hydrogel" according to the instant claim 1 (see cited as interest and prior art '582 col. 5; '938 [0014]).

Cited as Interest

US 2003/0143283 states "hydrogel such as a hyaluronate" for bone replacement (abstract, [0013]).

Chen et al (1995) states that "hydrogels of natural polymers especially polysaccharides have been used widely" and that "hyaluronate tends to form gels which are mucoadhesive" (pg. 69, col. 2, 1st paragraph; pg. 71, col. 1, last paragraph; and also see Table1 and Fig. 2 which show hyaluronate (or hyaluronic acid)).

Conclusions

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)272-6175. The examiner can normally be reached on M-F, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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